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Applicants: Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering III,
Sarwat Khattak, and Greg Randall

Serial No.: 10/053,929 Art Unit: Not Yet Assigned

Filed: January 22, 2002 Examiner: Not Yet Assigned

For: *POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*

Assistant Commissioner for Patents
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT

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Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including twelve (12) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/433,486, filed November 4, 1999, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: 10/053,929
 Filed: January 22, 2002
 INFORMATION DISCLOSURE STATEMENT

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<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: June 12, 2002

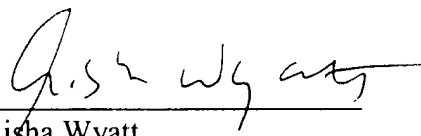
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INFORMATION DISCLOSURE STATEMENT

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/053,929	
		Filing Date	January 22, 2002	
		First Named Inventor	Julie Straub	
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		Examiner Name		
Sheet	of	12	Attorney Docket Number	ACU 109 CIP

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,382,437		Ecanow	01-17-1995	COPY OF PAPERS ORIGINALLY FILED
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/053,929 JUN 27 2002
		Filing Date	January 22, 2002
		First Named Inventor	Julie Straub
		Group Art Unit	
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Sheet 2 of 12	Attorney Docket Number	ACU 109 CIP	

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Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
		5,591,456		Franson, et al.	01-07-1997
		5,609,998		Texter, et al.	03-11-1997
		5,622,279		Czekai, et al.	09-02-1997
		5,622,938		Wong	04-22-1997
		5,657,931		Nair, et al.	08-19-1997
		5,662,883		Bagchi, et al.	09-02-1997
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		5,718,919		Ruddy, et al.	02-17-1998
		5,747,001		Wiedman, et al.	05-05-1998
		5,762,961		Roser et al.	06-09-1998
		5,919,434		Dugstad, et al.	07-06-1999
		5,976,574		Gordon, et al.	11-02-1999
		5,985,285		Titball, et al.	11-16-1999
		6,001,336		Gordon	12-14-1999

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office. ³	Number ⁴	Kind Code ⁵ (if known)		
		WO	98/31346	A1	Massachusetts Institute of Technology	07-23-1998
		WO	98/51282	A1	Imarx Pharmaceutical Corp.	11-19-1998

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		Filing Date	January 21, 2002		
		First Named Inventor	Julie Straub		
		Group Art Unit			
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Sheet	3	of	12	Attorney Docket Number	ACU 109 CIP

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		ADEYEYE & PRICE, "Chemical, dissolution stability and microscopic evaluation of suspensions of ibuprofen and sustained release ibuprofen-wax microspheres," <i>J. Microencapsul.</i> 14(3):357-77 (1997).	
		AHN, et al., "Enhancement of bioavailability of ketoprofen using dry elixir as a novel dosage form," <i>Drug Dev. Ind. Pharm.</i> 24(7):697-701 (1998).	
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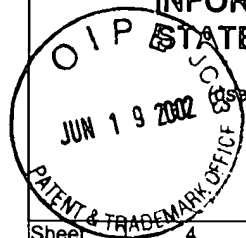
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number		10/053,929	
		Filing Date		January 22, 2002	
		First Named Inventor		Julie Straub	
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		BADIGER, et al., "Porogens in the preparation of microporous hydrogels based on poly(ethylene oxides)," <i>Biomaterials</i> 14:1059-63 (1993).	
		BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," <i>J. Pharm. Sci.</i> 78(11):964-67 (1989).	
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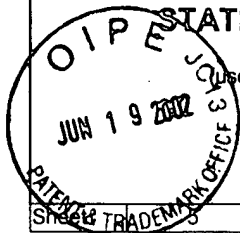
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		Application Number	10/053,929 JUN 27 2002
		Filing Date	January 22, 2002
		First Named Inventor	Julie Straub
		Group Art Unit	
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		CHIOU, et al., "Enhancement of dissolution rates of poorly water-soluble drugs by crystallization in aqueous surfactant solutions I: Sulfathiazole, Prednisone, and Chloramphenicol," <i>J. Pharm. Sci.</i> 65:1702-04 (1976).	
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		FENIMORE & LOY, "Injectible dispersion of Δ ⁹ -tetrahydrocannabinol in saline using polyvinyl pyrrolidone," <i>J. Pharm. Pharmacol.</i> 23:310- (1971).	

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		Filing Date		January 22, 2002	
		First Named Inventor		Julie Straub	
		Group Art Unit			
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Sheet 6 of 12	Attorney Docket Number		ACU 109 CIP		

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		FORD, "The current status of solid dispersions," <i>Pharm. Act. Helv.</i> 61:69-88 (1986).	
		FREITAS & MÜLLER, "Spray-drying of solid lipid nanoparticles (SLN™)," <i>Eur. J. Pharm. Biopharm.</i> 46(2):145-51 (1998).	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Use as many sheets as necessary)		Application Number	10/053,929 JUN 27 2002
		Filing Date	January 22, 2002
		First Named Inventor	Julie Straub
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Sheet 7 of 12	Attorney Docket Number	ACU 109 CIP	

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		HIRSCHBERG, et al., "Oral absorption of CGS-20625, an insoluble drug, in dogs and man," <i>J. Pharmacokinet. Biopharm.</i> 23(1):11-23 (1995).	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/053,929
		Filing Date	January 24, 2002
		First Named Inventor	Julie Straub
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		KHAN & JIABI, "Preparation, characterization, and dissolution studies of ibuprofen solid dispersions using polyethylene glycol (PEG), talc, and PEG-talc as dispersion carriers," <i>Drug Dev. Ind. Pharm.</i> 24(5):455-62 (1998).	
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		LEMOSENNA, et al., "Evaluation of the hydrophobic drug loading characteristics in nanoprecipitated amphiphilic cyclodextrin nanospheres," <i>Pharm. Dev. Tech.</i> 3:85-94 (1998).	
		LEUCUTA, et al., "The kinetics of nifedipine release from porous hydrophilic matrices and the pharmacokinetics in man," <i>Pharmazie</i> 43:845-48 (1988).	

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		LIN, et al., "Improved oral absorption of L-365260, a poorly soluble drug," <i>Biopharm. Drug Dispos.</i> 17(1):1-15 (1996).	
		LIN, et al., "Preparation of enteric-coated microspheres of <i>Mycoplasma hyopneumoniae</i> vaccine with cellulose acetate phthalate: (II). Effect of temperature and pH on the stability and release behaviour of microspheres," <i>J. Microencapsul.</i> 8(4):537-45 (1991).	
		MARTINDALE, <i>The Extra Pharmacopoeia</i> , 711 Dissolution, pp. 1791-92, 30th Ed. (The Pharmaceutical Press, London 1993).	
		MASON & WINER, "Kinetics of aspirin, salicylic acid, and salicylic acid following oral administration of aspirin as a tablet and two buffered solutions," <i>J. Pharm. Sci.</i> 70(3):262-65 (1981).	
		MIGLIARESI, et al., "Physical characterization of microporous poly(2-hydroxyethyl methacrylate) gels," <i>J. Biomed. Mater. Res.</i> 15:307-17 (1981).	
		MISHRA & YALKOWSKY, "A flat circular hole device for zero-order release of drugs: characterization of the moving dissolution boundary," <i>Pharm. Res.</i> 7(11):1195-97 (1990).	
		MORRIS, et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," <i>J. Pharm. Sci.</i> 81(12):1185-88 (1992).	
		NAJIB, et al., "The adsorption of hydrophilic polymers at the liquid-solid interface," <i>J. Pharm. Pharmac.</i> 29:43P (1977).	
		NISHIMURA, et al., "Dosage form design for improvement of bioavailability of levodopa VI: formulation of effervescent enteric-coated tablets," <i>J. Pharm. Sci.</i> 73(7):942-46 (1984).	
		NYSTRÖM & WESTERBERG, "The use of ordered mixtures for improving the dissolution rate of low solubility compounds," <i>J. Pharm. Pharmacol.</i> 38(3):161-65 (1986).	

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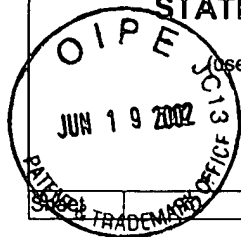
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		NYSTRÖM, et al., "Dissolution rate measurements of sparingly soluble compounds with the Coulter Counter model TALL," <i>J. Pharm. Pharmacol.</i> 37(4):217-21 (1985).	
		OTSUKA, et al., "Hygroscopic stability and dissolution properties of spray-dried solid dispersions of furosemide with Eudragit," <i>J. Pharm. Sci.</i> 82(1):32-38 (1993).	
		PACE, et al., "Novel injectable formulations of insoluble drugs," <i>Pharmaceutical Technology</i> 116-34 (March 1999).	
		PILLAY & FASSIHI, "A new method for dissolution studies of lipid-filled capsules employing nifedipine as a model drug," <i>Pharm. Res.</i> 16(2):333-37 (1999).	
		REDDY, et al., "Dissolution characteristics and oral absorption of digitoxin and digoxin coprecipitates," <i>J. Pharm. Sci.</i> 65(12):1753-58 (1976).	
		RIDOLFO, et al., "Benoxaprofen, a new anti-inflammatory agent: particle-size effect on dissolution rate and oral absorption in humans," <i>J. Pharm. Sci.</i> 68(7):850-52 (1979).	
		SAANO, et al., "Relative pharmacokinetics of three oral 400 mg ibuprofen dosage forms in healthy volunteers," <i>Int. J. Clin. Pharm. Ther. Toxic.</i> 29:381-85 (1991).	
		SCHRÖDER & SABEL, "Nanoparticles, a drug carrier system to pass the blood-brain barrier, permit central analgesic effects of i.v. dalargin injections," <i>Brain Research</i> 710:121-24 (1996).	
		SERAJUDDIN, et al., "Effect of vehicle amphiphilicity on the dissolution and bioavailability of a poorly water-soluble drug from solid dispersions," <i>J. Pharm. Sci.</i> 77(5):414-17 (1988).	
		SERAJUDDIN, et al., "Improved dissolution of a poorly water-soluble drug from solid dispersions in polyethylene glycol: polysorbate 80 mixtures," <i>J. Pharm. Sci.</i> 79(5):463-64 (1990).	

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		SERAJUDDIN, et al., "Water migration from soft gelatin capsule shell to fill material and its effect on drug solubility," <i>J. Pharm. Sci.</i> 75(1):62-64 (1986).	
		SUZUKI & SUNADA, "Comparison of nicotinamide, ethylurea, and polyethylene glycol as carriers for nifedipine solid dispersion systems," <i>Chem. Pharm. Bull.</i> 45:1688-93 (1997).	
		SUZUKI & SUNADA, "Influence of water-soluble polymers on the dissolution of nifedipine solid dispersions with combined carriers," <i>Chem. Pharm. Bull.</i> 46:482-87 (1998).	
		SWEETANA & AKERS, "Solubility principles and practices for parenteral drug dosage form development," <i>PDA J. Pharm. Sci. Technol.</i> 50(5):330-42 (1996).	
		TAKENAKA, et al., "Preparations of solid particulates of theophylline-ethylenediamine complex by a spray-drying technique," <i>J. Pharm. Sci.</i> 71(8):914-19 (1982).	
		TAKEUCHI, et al., "Enhancement of the dissolution rate of a poorly water-soluble drug (tolbutamide) by a spray-drying solvent deposition method and disintegrants," <i>J. Pharm. Pharmacol.</i> 39(10):769-73 (1987).	
		TASIC, et al., "The influence of beta-cyclodextrin on the solubility and dissolution rate of paracetamol solid dispersions," <i>J. Pharm. Pharmacol.</i> 44(1):52-55 (1992).	
		TINGSTAD, et al., "Dissolution rate studies. III. Effect of type and intensity of agitation on dissolution rate," <i>J. Pharm. Sci.</i> 62(2):293-97 (1973).	
		TORRADO, et al., "Egg albumin microspheres containing paracetamol for oral administration. I. In vitro characterization," <i>J. Microencapsul.</i> 7(4):463-70 (1990).	
		TRAUE, et al., "Spray products of sparingly soluble drugs. 1. In vitro study of spray products of nitrazepam in a starch hydrolysis product," <i>Pharmazie.</i> 43(5):368-69 (1988).	

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		VÉLAZ, et al., "Effect of PEG 4000 on the dissolution rate of naproxen," <i>Eur. J. Drug Metab. Pharmacokinet.</i> 23(2):103-08 (1998).	
		VENKATARAM & ROGERS, "Characteristics of drug-phospholipid coprecipitates I: Physical properties and dissolution behavior of griseofulvin-dimyristoylphosphatidylcholine systems," <i>J. Pharm. Sci.</i> 73(6):757-61 (1984).	
		VUDATHALA & ROGERS, "Dissolution of fludrocortisone from phospholipid coprecipitates," <i>J. Pharm. Sci.</i> 81(3):282-86 (1992).	
		WAN, et al., "Plasticizers and their effects on microencapsulation process by spray-drying in an aqueous system," <i>J. Microencapsul.</i> 9(1):53-62 (1992).	
		WESTERBERG, et al., "Physicochemical aspects of drug release. IV. The effect of carrier particle properties on the dissolution rate from ordered mixtures," <i>Int. J. Pharm.</i> 28:23-31 (1986).	
		YAMAOKA, et al., "Comparison of body distribution of poly(vinyl alcohol) with other water-soluble polymers after intravenous administration," <i>J. Pharm. Pharmacol.</i> 47:479-86 (1995).	
		YAMAOKA, et al., "Fate of water-soluble polymers administered via different routes," <i>J. Pharm. Sci.</i> 84(3):349-54 (1995).	

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